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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,407	10/30/2003	Toyonobu Tanaka	03-211	7232

7590 07/12/2006

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EXAMINER	
MORILLO, JANELL COMBS	
ART UNIT	**PAPER NUMBER**
1742	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,407	TANAKA ET AL.	
	Examiner	Art Unit	
	Janelle Combs-Morillo	1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *091205*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 12-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 26, 2006.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuo (US 2002/0033717).

Matsuo teaches a biocompatable titanium alloy consisting of (in at%): 5% Nb, 1% Al, 5% V, 15% Zr, balance titanium (Table 1), which falls within the presently claimed composition ranges (cl. 1-3). Though Matsuo does not specify said alloy is superelastic, because the composition taught by Matsuo falls within the presently claimed alloying ranges, substantially the same degree of superelasticity is inherintly expected for Matsuo as in the instant alloy. Because the prior art teaches an identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP 2112.01. Therefore, Matsuo anticipates the presently claimed invention.

Concerning claim 6, Matsuo teaches said biocompatable Ti alloy can be used for medical instuments [0004]. Though Matsuo does not mention the particular presently claimed medical products, the phrase "the alloy is for use in..." as claimed is held to define merely an intended use for the alloy composition. Because the prior art teaches an alloy suitable for medical instruments, said alloy appears to be capable of performing said intended use as recited. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997), MPEP 2111.02.

Concerning claim 10, Matsuo teaches said biocompatable Ti alloy can be used for spectacle frames [0004].

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-6, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo (US 2002/0033717) in view of "ASM Handbook Vol. 2" p 599.

Matsuo is discussed in paragraphs above.

Though Matsuo does not specify said alloy is superelastic, because the prior art teaches an identical chemical structure, the properties applicant discloses and/or claims are necessarily present. The examiner asserts that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially

identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. The prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), see MPEP 2112.01.

Matsuo teaches that 0.1-10at% Sn can be added to said Ti alloy (see Matsuo at cl. 10, 11), which "ASM Handbook Vol. 2" teaches is an alpha stabilizer, used to achieved higher strength without embrittlement (p 599). It would have been obvious to one of ordinary skill in the art to select Sn out of the markush group taught by Matsuo, because "ASM Handbook Vol. 2" teaches that Sn is benefitical to achieve higher strength without embrittlement (p 599).

6. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo (US 2002/0033717) and "ASM Handbook Vol. 2" p 599 in view of Hanada (US 6,786,984).

Matsuo does not teach forming said Ti alloy into guide wires, stents. However, Hanada teaches that biocompatable Ti alloys can be used for stents and guide wires (column 4 lines 10, 13). It would have been obvious to one of ordinary skill in the art to form the alloy taught by Matsuo into a stent or guide wire, because Matsuo teaches said alloy has good biocompatability and can be formed into a variety of medical instruments.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo or Hanada and "ASM Handbook Vol. 2" p 599 in view of Gotanda (US 4,987,314).

Neither Matsuo nor Hanada teach forming said Ti alloy into actuator of an endoscope. However, Gotanda teaches that biocompatable Ti alloys (column 4 line 66) can be used for actuators of an endoscope (abstract, column 3 lines 59-60). It would have been obvious to one of ordinary skill in the art to form the alloy taught by Matsuo or Hanada into a actuator of an endoscope, because Matsuo teaches said alloy has good biocompatability and can be formed into a variety of medical instruments (Matsuo at [0004]), or because Hanada teaches said alloy has high biocompatability (column 1 lines 42-47).

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanada (US 6,786,984) and "ASM Handbook Vol. 2" p 599.

Hanada teaches a biocompatable titanium alloy comprising (in at%): 3-6at% Sn, 8-20at% Nb, balance titanium (column 10, claims 1 and 3). Hanada teaches said alloy is superelastic and exhibits shape memory effect (column 9 lines 30-33). Though Hanada does not teach the addition of Mo, Al, Ge, Ga, or In; Hanada does teach that Mo has moderate biocompatability (Fig. 1). Furthermore, "ASM Handbook Vol. 2" teaches that Mo is added to titanium alloys for the known purpose of (as a beta stabilizer) promoting hardenability and short-time elevated temperature strength (p 599, 3rd column). Addtionally, "ASM Handbook Vol. 2" teaches Ge and Ga are added to titanium alloys for the known purpose of stabilizing the alpha crystal structure. Changes in concentration or temperature will generally not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical, i.e. they produce a new and unexpected result. "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the instant case, the addition of Ge, Ga, and Mo are held to be result effective variables, wherein the expected result is stabilization of the crystal structure and/or promoting hardenability and elevated temperature strength. Therefore, it would have been obvious to one of ordinary skill in the art to add Mo, Ge, or Ga as taught by "ASM Handbook Vol. 2" to the titanium alloy taught by Hanada, for the above mentioned recognized result.

Therefore, it is held that the alloy taught by the combination of Hanada and "ASM Handbook Vol. 2" overlaps the ranges of instant claims 1-5. Overlapping ranges have been held to be a prima facie case of obviousness, see MPEP § 2144.05. It would have been obvious to one of ordinary skill in the art to select any portion of the range, including the claimed range, from the broader range disclosed in the prior art, because the prior art finds that said composition in the entire disclosed range has a suitable utility.

Concerning claims 6-9, Hanada teaches that said biocompatable Ti alloys can be used for stents, guide wires (column 4 lines 10, 13), orthodontic wire (column 4 lines 29-30).

Concerning claim 10, because Hanada teaches said alloy is formable into drawn wires, etc. (column 4 lines 43-52) it would have been obvious to one of ordinary skill in the art to draw said alloy into a frame for eyeglasses or a nose pad arm.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Combs-Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 8:30 am- 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GEORGE WYSZOMIERSKI
PRIMARY EXAMINER
GROUP 1700

JCM
July 5, 2006